IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application. No.

10/535,108

Confirmation. No.

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1616

Applicant(s)

Hans-Kervin Bruins et al.

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Title

Arthropod Repellent Comprising Extracts and/or Parts

of the Plant Vitex Agnus-Castus

TC/A.U.

Examiner

Ali Soroush

Docket No.

GIL-16108

Mail Stop Appeal Brief-Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

This Appeal Brief is being filed in response to the Office Action of 10 November 2009 and pursuant to the Notice of Appeal filed 9 February 2010.

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I. REAL PARTY IN INTEREST

The real party in interest or owner of the present application and the technology and inventions embodied therein is Alpha-Biocare GmbH, whose principal mailing address is LifeScience Center, Merowinger Platz 1a, Düsseldorf, Germany, 40225. An assignment transferring rights from the inventors to Ferro Corporation was recorded 2 August 2005 at Reel 016604, Frame 0907.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

The application included 27 claims as originally filed on 5 October 2005. In a Preliminary Amendment filed together with the application, claims 2-20 and 23025 were amended.

In a first Office Action mailed on 15 November 2007, the Examiner rejected claims 21-27 under 35 U.S.C. 101, rejected claims 9, 10, 14, and 18-20 under 35 U.S.C. 112, second paragraph, and rejected claims 1-20 under 35 U.S.C. 103(a) over the Ito and Gardiner references.

In an Amendment filed 14 February 2008, Appellants canceled claims 1-27 and added new claims 28-42 and filed an Information Disclosure Statement therewith.

In a second Office Action mailed 28 May 2008, the Examiner levied a constructive restriction requirement, effectively eliminating all pending claims from consideration. In an Amendment filed 24 June 2008, Appellants added new claims 43-52.

In a Final Office Action mailed 8 October 2008, the Examiner, while not specifically discussing the constructive restriction requirement in the previous Office Action, proceeded with examination of all pending claims, 28-52. Claims 28-32, 34-36 and 40-42 were rejected under 35 U.S.C. 103(a) over the Blum, Watanabe and Hernandez references, while claims 28, 29, 31-34 and 36-52 were rejected over the Ross, Watanabe and Hernandez references.

On 10 December 2008, Appellants filed a Request for Continued Examination under 37 C.F.R. 1.114, wherein claims 28, 43 and 45 were amended, and wherein claims 42 and 46-52 were canceled, leaving claims 28-41 and 43-45 pending.

In an Office Action mailed 17 March 2009, the Examiner rejected claims 28-41 under 35 U.S.C. 112, second paragraph, claims 28, 29, 31-33, 36-41 and 43-45 under 35 U.S.C. 103(a) over a combination of the Uick, Abivardi, and Beldock references. Claims 30, 34, and 35 were rejected under 35 U.S.C. 103(a) over a combination of the Uick, Abivardi, Blum and Beldock references.

Appellants filed an Amendment on 7 August 2009 amending claims 28, 30, and 40, and canceling claim 41, leaving claims 28-40 and 43-45 pending.

On 10 November 2009, a Final Office Action was mailed, maintaining the rejection of claims 28, 29, 21-33, 36-41 and 43-45 under 35 U.S.C. 103(a) over the Uick, Abivardi and

Beldock references, and maintaining the rejection under 35 U.S.C. 103(a) of claims 30, 34, and 35 under 35 U.S.C. 103(a) over the Uick, Abivardi, Blum and Beldock references.

On 9 February 2010, Appellants filed a Notice of Appeal, because there is at least one actual issue for appeal.

In summary, claims numbering as high as 52 have at one point been pending in the application. During the prosecution thus far, claims 1-27, 41, 42, and 46-52 have been canceled, leaving claims 28-40 and 43-45 pending as of this writing.

Claims 28-40 and 43-45 stand finally rejected, and all such claims are pending on appeal. The pending claims are set forth in the Claims Appendix, which is attached hereto for the convenience of the Board.

IV. STATUS OF AMENDMENTS

No amendments were filed in the application subsequent to the Office Action mailed 10 November 2009.

V. SUMMARY OF CLAIMED SUBJECT MATTER

As characterized in the Abstract:

The present invention includes portions or extracts of any kind, which can be obtained from the plant *Vitex agnus-castus* (monk pepper) and can be used as repellent against bothersome, lymph- and/or blood-sucking, skin penetrating, respectively food-, storage materials--or plant--damaging arthropods (mites, ticks, insects). Thus, this repellent protects the health of humans, pet animals and livestock, plants and stored materials.

In the remainder of the Summary, citation formats will follow this format: "page/line," for example "4/18" and "[paragraph]," for example [0029], with multiple citations for the same limitation separated by a semicolon. Such format is believed to be clear.

In particular, independent claim 28 recites a method of repelling ticks and mites comprising:

applying to a product, area or surface desired to be free of ticks and mites (5/19),

a repellent composition (6/26) comprising at least one portion of the plant Vitex agnuscastus selected from the group consisting of extracts of said plant, parts of said plant, and combinations thereof (5/17-20).

Also, independent claim 43 is directed to a repellent composition for repelling ticks and mites, comprising:

extracts, and/or parts of the plant Vitex agnus-castus (5/17-20), and

a component selected from the group consisting of N,N-diethyl-m-toluamide dimethyl phthalate (3/20), 2-ethyl-hexane-1,3-dol, isopulegol, 1-piperidine carboxylic acid, hydroxy-ethyl-isobutyl-piperidine-carboxylate, and combinations thereof (3/33-4-1).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- 1. Whether claims 28, 29, 31-33, 36-41, and 43-45 were properly rejected under 35 U.S.C. 103(a) as being unpatentable over Uick, U.S. Pat. No. 5,716,602, ("Uick") in view of Abivardi, Iranian Entomology an Introduction Applied Entomology Vol. 2, ("Abivardi"), as evidenced by Beldock et al., U.S. Pat. No. 5,648,398, ("Beldock").
- 2. Whether claims 30, 34 and 35 were properly rejected under 35 U.S.C. 103(a) as being unpatentable over Uick, in view of Abivardi, and further in view of Blum et al., U.S. Pat. No. 5,885,600, ("Blum"), as evidenced by Beldock.

VII. ARGUMENT

A. Claims 28, 29, 31-33, 36-41, and 43-45 (Grouped) Were Improperly Rejected Under 35 U.S.C. § 103(a) over a combination of the Uick, Abivardi and Beldock references.

The Examiner has rejected claims 28, 29, 31-33, 36-41, and 43-45 under 35 U.S.C. 103(a) as obvious in view of the Uick, Abivardi and Beldock references. Such rejection is principally based on the Examiner's belief that Uick discloses an insect repellent sunscreen comprising DEET, octyl methoxycinnamate, fragrance, emulsifiers, and water which can be applied onto human skin for protection outdoors against annoyance by pests and the harmful effects of UV rays. The Examiner admits that Uick fails to teach that the repellent composition comprises a portion or extract of the plant Vitex agnus-castus.

Accordingly, the Examiner cites Abivardi for an alleged teaching of a composition of pine seed with leaves of Vitex agnus castus that can be cooked in olive oil and rubbed onto the entire body as a "repellent against insects and other injurious animals," p. 458. Furthermore, Abivardi teaches that the leaves of Vitex agnus castus can be scattered in the house including on the floors in order to repel insects or vermin by their odor.

The Examiner cites Beldock as evidence that DEET is effective against Lyme disease ticks, and concludes that it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add the leaves of Vitex agnus-castus as an insect repellent to the composition of Uick, as suggested by Abivardi and produce the instant invention. The Examiner believes that the skilled artisan would have been motivated to do this because Abivardi teaches that the leaves of Vitex agnus castus act as an insect repellent.

Based on Beldock, the Examiner takes the position that a composition comprising DEET would necessarily act as a tick repellent. The Examiner concludes that it would have been obvious to use the leaves of Vitex agnus-castus as an insect repellent to be added to the composition taught by Uick in order to enhance the insect repellency activity of the composition.

To properly determine a *prima facie* case of obviousness, the Examiner "must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made," M.P.E.P. 2142. Three criteria may be helpful in determining whether claimed subject matter is obvious under section 103(a):

first, if there is some suggestion or motivation to modify or combine the cited references; second, if there is a reasonable expectation of success; and third, if the prior art references teach or suggest all the claim limitations, *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 127 S.Ct. 1727 (2007). With regard to the first criterion, the mere fact that references an be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re *Mills*, 916 F.3d 690 (Fed. Cir. 1990). "Knowledge in the prior art of every element of a patent claim ... is not of itself sufficient to render the claim obvious," *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966); *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1333-34 (Fed. Cir. 2002). The issue is whether there is an apparent reason to combine the known elements in the fashion claimed by the patent at issue. *KSR Int'l Co. v. Teleflex, Inc.*

The Examiner has cited three references, which, when taken together, appear to disclose all limitations of the rejected claims. However, the Examiner, in merely pointing out the existence of all limitations of a claim in a collection of prior art references does not establish the unpatentability of such claim. Indeed, neither the prior art nor the knowledge of the skilled artisan suggests the desirability of the combination of Uick, Abivardi and Beldock. Uick is cited only for a disclosure of DEET, a purely chemical insect repellent. It has no relation to the instantly claimed composition as no DEET is present therein. Further, Uick fails to disclose or suggest any plant extract whatsoever, and in particular, fails to disclose *Vitex agnus castus*, which is the focus of all claims under consideration herein.

The key to the instant rejection appears to be Abivardi's teaching that leaves of *Vitex* agnus-castus can be cooked with olive oil and pine seed to repel insects. This disclosure, and its combination with Uick and Beldock, does not lead the skilled artisan to the claimed invention for two reasons.

Initially, Appellants note that the entire entry of Abivardi on this point (on page 458) is: "3. Pine seed with the leaves of Abraham's balm (*Vitex agnus-castus*) or with Eberraute (*Artemisia abrotanum*)." It is clear, in the opinion of the original author in Abivardi, that Abraham's balm is interchangeable with Eberraute. Because the two species are so different from one another as to be members of different taxonomic Orders, there would be no reason to believe that they would have the same or similar properties. Hence, the Abivardi reference

would tend to teach that it is Pine seed, because it is listed first, rather than either Abraham's balm or Eberraute, which provides the insect repellent property.

In the alternative, it must be pointed out, however, that insects are not arachnids. Indeed, ticks and mites are completely different from mosquitoes. Ticks and mites are arachnids (arachnida), whereas mosquitoes are insects (insecta). In particular, arachnids have 8 legs, an undivided body and no wings. Arachnids bite and draw blood for a period of up to 12 days continuously, and when they do, they bite and draw blood from the upper layers of the skin. Arachnids draw blood in all development stages: larva, nymph and adult. They develop in a dry environment and have a life span of 3-10 years.

On the other hand, mosquitoes have six legs and a body which is divided into three parts with wings. They bite and draw blood for a period of only several seconds and bite directly into blood vessels. It is only the female adults that bite and draw blood. Mosquitoes are born in and develop in the water, and their lifetime is only one to two months.

Indeed, insects recognize their host, e.g. humans, from a distance, up to 100 meters. Consequently, insect repellents are volatile substances, in particular essential oils, which remain on the skin only for a short period. Cigarette smoke acts in a similar way to repel insects.

On the other hand, ticks do not recognize their host from a distance, but get onto a host when it comes in contact with the grass or plants on which they are sitting. Only close proximity of the host attracts a tick. Repellents against ticks, therefore, must remain on the skin for a long time. Ticks are not repelled by cigarette smoke.

Known insect repellents, such as lemongrass oil, lemon oil, clove oil or many other etheric (i.e., essential) oils, have no repelling effect on ticks and mites. Chemical insect repellents, in particular the well known DEET, as well as Icaridine, have a very weak effect on ticks. Thus, in commercial repellents against ticks, the active ingredients have to be used in a very high concentration compared to repellents against mosquitoes. In the context of these facts, the prior art has to be evaluated as follows.

Based on the stark differences between arachnids and mosquitoes (insects), it cannot be expected that a repellent which is appropriate for repelling insects such as mosquitoes is also effective as a repellent against arachnids such as ticks and mites.

Further, the Examiner appears to proceed from an assumption that plant extracts have

generalizable activities and effects, i.e., that when the activity of one plant extract is known, such knowledge will arguably foretell the activity of another plant extract. Such effects are not generalized. Constituents of plant extracts vary widely, even among species within the same family or genus. It cannot be presumed that if a first plant extract has a repellent activity against certain *insects*, than an extract from a completely different plant would necessarily have a repellent effect against ticks and mites, i.e., *arachnids*.

The present invention involves only extracts from *Vitex agnus castus*, not extracts from the broader genus *Vitex* in general, since even between different species of the same genus, there are significant differences in the components of such extracts. For example, even the plant *Vitex agnus castus* as presently claimed has different components than *Vitex rotundifolia*, That means, even within one genus there are significant differences in the components of the various species.

It is well known that certain plant extracts such as citrus oil can act as a repellent against insects, in particular mosquitoes, However, from this repellent property against insects, it cannot be concluded that there is also an activity against ticks and mites, which are completely different animals (arachnids). In the same way, from an insect repellent activity of one plant extract, it cannot be concluded that any other plant extract would also show an insect repellent activity, that alone a repellent activity against ticks and mites.

Mosquito repellence activity (i.e., insect repellence), as evaluated against *Aedes aegypti* was mainly confined to the most polar fractions of a plant extract, (Hebbalkar, et al., 1992; Mosquito repellent activity of oils from *Vitex negundo* leaves). In contrast, the repellent constituents of *Vitex agnus-castus* seeds are extractable only with *non-polar* solvents.

Based on the foregoing, it is unforeseeable that extracts of *Vitex agnus-castus* would have a repellent effect against arachnids, and therefore the Examiner's *prima facie* case of obviousness fails. Appellants believe the non-obviousness of claims 28, 29, 31-33, 36-41, and 43-45 has been established, and respectfully request that the Board overturn the rejection.

B. Claims 30, 34 and 35 were improperly rejected under 35 U.S.C. 103(a) as being unpatentable over Uick, in view of Abivardi, and further in view of Blum et al., U.S. Pat. No. 5,885,600, ("Blum"), as evidenced by Beldock.

Claims 30, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uick, in view of Abivardi, and further in view of Blum et al., U.S. Pat. No. 5,885,600, ("Blum"), as evidenced by Beldock. The Examiner admits that Uick and Abivardi fail to teach a repellent composition comprising antioxidant. This deficiency is cured by the teachings of Blum, by its alleged teachings that insect repellents are used to prevent insects from annoying humans and animals, as well as repellents in general, which have been used to prevent insect harm to such items as food, clothing, and furniture.

The Examiner alleges that a composition having insect repellent properties can be made from cold processed extracted oils and an antioxidant, and may also include a solvent, UV absorber or stabilizer, and antioxidants. Such a combination of ingredients may be formulated into products such as such as lotions, sprays, and creams for use on humans, animals and vegetation, which is effective against arachnids such as spiders, ticks, and mites. The Examiner concludes that it would have been obvious to the skilled artisan to add antioxidants to the composition of Uick, (as suggested by Blum) to produce the instant invention. One of ordinary skill in the art would have allegedly been motivated to do this because Blum teaches that insect repellent compositions can comprise antioxidants.

Initially, Appellants note that the patentability of claim 28 has been established amply hereinabove. Each of claims 30, 34, and 35 ultimately depends from claim 28. The additional citation of Blum does not disturb the patentability of claim 28, and hence claims 30, 34, and 35 are patentable over the cited prior art combination.

Appellants further note that Blum discloses a variety of oils and extracts wholly unrelated to the instantly claimed compositions, in particular, neem, citronella and cedar oil. Appellants note that *Vitex agnus castus* is from the family Verbenaceae, while Cedar oil is derived from cedar wood (family Pinaceae), citronella is an extract of citrus fruit (family Rutaceae) and Neem is derived from the Neem tree, (*Azadirachta indica*, of the family Mellaceae). There is no relationship among the extracts of Blum and those instantly claimed. There is no reason, *ab*

initio, to suppose that extracts of one will have properties similar to extracts of another.

Blum discloses insect repellents from cold processed extracted oils and an antioxidant, in particular oils from Neem, Citronella, and Cedarwoods. The focus is on insects (Abstract), although in col. 6, line 20 ticks and mites are mentioned. By cold-pressing and addition of antioxidants, the effectiveness of the repellent can be maintained for a long time. As does the instant specification, Blum discloses that essential oils from plants have long been known as insect repellents. Blum is completely silent about *Vitex agnus castus* or any species of *Vitex*. The disclosure of Blum is not enabling for a repellent against ticks, as there is no example showing any effect against them. It appears that the citation of Blum is further testimony to the Examiner's apparent belief that any plant extract or essential oil can be used to repel insects.

Based on the foregoing, Appellants assert the patentability of claims 30, 34, and 35, and respectfully request that the Board overturn the rejection.

4. Conclusion

In view of the foregoing, it is respectfully submitted that claims 28-40 and 43-45 are allowable, and a ruling from the Board to that effect is therefore respectfully requested.

Respectfully submitted,
RANKIN, HILL & CLARK, L.L.P.

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CLAIMS APPENDIX

Claims 1-27 (cancel)

Claim 28 (rejected): A method of repelling ticks and mites comprising applying to a product, area or surface desired to be free of ticks and mites, a repellent composition comprising at least one portion of the plant Vitex agnus-castus selected from the group consisting of extracts of said plant, parts of said plant, and combinations thereof.

Claim 29 (rejected): The method of claim 28 wherein portions or extracts of the plant Vitex agnus-castus are selected from the group consisting of semen, fruits, leaves, stalks, roots, and combinations thereof.

Claim 30 (rejected): The method of claim 28 wherein the product, area, or surface desired to be free of ticks and mites is selected from the group consisting of textiles, furs, food, and agricultural products.

Claim 31 (rejected): The method of claim 28 wherein the composition further comprises at least one dermatologically acceptable carrier.

Claim 32 (rejected): The method of claim 28 wherein the composition further comprises at least one ingredient used for skin care of humans or animals.

Claim 33 (rejected): The method of claim 28 wherein the composition further comprises at least one perfume.

Claim 34 (rejected): The method of claim 28 wherein the composition further comprises an antioxidant.

Claim 35 (rejected): The method of claim 34 wherein the antioxidant is selected from selected

from the group consisting of 6-O-palmitoyl-L-ascorbic acid, 2,6-di-tert-butyl-4-methylphenol, and combinations thereof.

Claim 36 (rejected): The method of claim 28 wherein the composition further comprises a UV absorber.

Claim 37 (rejected): The method of claim 36 wherein the UV absorber is selected from the group consisting of titanium oxide, octyl methoxycinnamate, and combinations thereof.

Claim 38 (rejected): The method of claim 28 wherein the composition further comprises a second repellent compound.

Claim 39 (rejected): The method of claim 38 wherein the second repellent compound is selected from the group consisting of N,N-diethyl-m-toluamide; dimethyl phthalate; N,N-diethylbenzamide; 2-ethyl-hexane-1,3-diol; p-methane-3,8-diol; isopulegol; 1-piperidine carboxylic acid; hydroxy-ethyl-isobutyl piperidine-carboxylate; essential oils of plants other than Vitex agnus-castus; derivatives of the foregoing, and combinations of all of the foregoing.

Claim 40 (rejected): The method of claim 28 wherein the product, area or surface desired to be free of ticks and mites is selected from the group consisting of skin, hair, and clothes.

Claims 41-42 (cancel)

Claim 43 (rejected): A repellent composition for repelling ticks and mites, comprising extracts, and/or parts of the plant Vitex agnus-castus, and a component selected from the group consisting of N,N-diethyl-m-toluamide dimethyl phthalate, 2-ethyl-hexane-1,3-dol, isopulegol, 1-piperidine carboxylic acid, hydroxy-ethyl-isobutyl-piperidine-carboxylate, and combinations thereof.

Claim 44 (rejected): The composition of claim 43 further comprising components for protection of food, animals, plants or stored materials.

Claim 45 (rejected): The composition of claim 43, wherein the portions of the plant or extracts are selected from the group consisting of semen, fruits, leafs, stalks, roots and combinations thereof.

Claims 46-52 (cancel)

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.